Readoption Review

State Cancer Registry 410 IAC 21-1

IC 4-22-2.5-3.1(c) requires an agency to conduct a review to consider whether there are alternative methods of achieving the purpose of the rule that are less costly or less intrusive, or that would minimize the economic impact of the proposed rule on small business.

Description of Rule:

The Indiana State Department of Health (ISDH) has responsibility for the establishment of a statewide cancer registry to be used in cancer prevention and control. According to IC 38-16-2, ISDH must establish a cancer registry for the purpose of recording all cases of malignant disease and certain other reportable tumors and precancerous diseases that are diagnosed or treated in Indiana in order to compile information for epidemiologic surveys of cancer and to apply appropriate preventive and control measures. Rule 410 IAC 21-1 details how these cases must be reported. In 1996, the Indiana General Assembly enacted IC 4-22-2.5 to establish automatic expiration of any rule in effect for more than seven years, and to create a streamlined method for readoption of such rules without change. On July 11, 2001, in accordance with IC 16-38-2, ISDH readopted 410 IAC 21-1 to establish methods for reporting cancer and certain other related cases to the Indiana State Cancer Registry (ISCR). In accordance with IC 4-22-2.5, 410 IAC 21-1 must be readopted if it is to remain in effect.

Readoption Analysis:

1) Is there a continued need for this rule?

Yes. IC 16-38-2 establishes the Indiana State Cancer Registry (ISCR) and requires hospitals, physicians, dentists, medical laboratories, surgery centers, and health facilities to report specified cases according to certain methods. Statute mentioned remains in effect so there is a continued need for rule 410 IAC 21-1 to require reporting. In addition, ISCR received federal grant funds totaling \$802,488 in fiscal year 2006-2007 from the Centers for Disease Control and Prevention (CDC) through the National Program of Cancer Registries Act, P.L. 102-515. In order to continue receiving federal grant funds, P.L. 102-515 requires Indiana to "provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations...." It goes on further to specify eight criteria that must be included in the regulations, most of which are included in the current rule.

2) What is the nature of any complaints or comments received from the public, including small business, concerning the rule or the implementation of the rule by the agency?



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Since the effective date of the rule, there have been no complaints or comments received from the public or small business concerning this rule or the implementation of this rule by the ISDH.

3) Examine the complexity of the rule, including difficulties encountered by the agency in administering the rule and small businesses in complying with the rule.

ISDH is not aware of any difficulties in administration of or compliance with this rule. This rule is somewhat complex and there are certain sections that need to be updated. Reporting entities that are affected by this rule have been able to comply with the rule, but after the readoption process is complete, a more thorough review of this rule should be undertaken.

4) To what extent does the rule overlap, duplicate, or conflict with other federal, state, or local laws, rules, regulations, or ordinances?

Rule 410 IAC 21-1 has some overlap, duplication, and conflict with state law IC 16-38-2 and federal law P.L. 102-515. Certain provisions required in the federal regulations may be lacking or ambiguous in the current 410 IAC 21-1. There are some minor conflicts between the state and federal laws, but these will be addressed at a later time after a thorough study of needed revisions is undertaken.

5) When was the last time the rule was reviewed under this section or otherwise evaluated by the agency, and the degree to which technology, economic conditions, or other factors have changed in the area affected by this rule since that time?

This is the first review of the rule since it became readopted July 11, 2001. Several coding rules and manuals have been revised since then, necessitating a more thorough review of the rule in the future. Because of the complexity of the changes, more time is needed than this current readoption process allows. The Indiana State Cancer Registry will work with Office of Legal Affairs on updating the rule over the course of the next year.